

REMARKS / ARGUMENTS

Claims 1, 10 and 14 are amended to more distinctly claim the subject matter of this invention. Claims 1 and 10 are amended as suggested by the Examiner. Support for the other amendments is clear from the specification.

Claims 1, 10 and 14 were rejected under 35 USC 103(a) over Theising et al in view of Estey et al. Applicants request reconsideration and withdrawal of this rejection for the reasons that follow.

Theising et al, at page 3198, the first sentence in the second paragraph under Discussion, indicates that the possibility for antagonism between STI571 and antileukemic agents was a major reason for undertaking the studies. The reasoning for this concern is explained in the same paragraph. The studies described in the reference indicate that no antagonism was seen between STI571 and most of the agents in the cell lines studied.

However, synergistic effects are claimed by the reference only for the combination of ara-C with STI571 and such synergistic effects appear to be reported only in a bcr-abl positive CML cell line, the K562 cell line. See, page 3197, column 2, first full paragraph. The reference speculates that bcr-abl expression may render cells resistant to chemotherapeutic agents and that treatment with STI571 rendered the cells susceptible to the chemotherapeutic agent. See, page 3198, second column, first and second full paragraphs. Thus, Theising et al reasonably leads one of skill to expect only that STI571 would enhance the effect of a chemotherapeutic agent on cells that express bcr-abl and for synergy with ara-C in such cells.

Estey et al is relied on as disclosing treatment of AML and myelodysplastic syndrome with the FAI combination of drugs. However, the secondary reference does not indicate that the patients studied expressed bcr-abl or any showed resistance to the FAI regimen due to bcr-abl expression. Since the study reported in Theising et al provides expectations only with respect to cells that express bcr-abl, the skilled artisan would not have a reasonable expectation of success when adding STI571 to the drug combination used in Estey et al on patients that were not reported to express bcr-abl.

The Examiner appears to acknowledge that the data presented in the present Examples demonstrates synergy for the claimed combinations at certain concentrations. Applicants assert that such data is sufficient to support the patentability of the presently claimed invention.

Applicants further assert that Theising et al clearly discloses that the effect of combining treatments is not predictable. Although the reference reports synergy when STI571 is added to ara-C, it is silent with respect to combinations of three or more of the agents studied. Indeed, it makes no suggestion that such combinations should be studied in CML or any other condition. Therefore, since synergy demonstrated for the claimed combinations was not suggested by the references, no further comparisons are required to demonstrate the patentability of the claimed invention.

For the reasons discussed above, Applicants request withdrawal of the rejection under 35 USC 103.

Entry of this amendment and reconsideration and allowance of the claims are respectfully requested.

Novartis Pharmaceuticals Corp.
Patents Pharma
One Health Plaza, Building 104
East Hanover, NJ 07936-1080
(862) 778-7824

Date: 08-28-08

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "George R. Dohmann", written over a horizontal line.

George R. Dohmann
Attorney for Applicants
Reg. No. 33,593